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(54) Title: METHOD AND KIT FOR THE TREATMENT OR PREVENTION OF COSMETIC SKIN CONDITIONS

(57) Abstract: The invention provides a method for the treatment of an area of the skin and/or subcutaneous tissue, and in particular for the cosmetic treatment of cellulite, comprising exposing the treatment area to ultrasound either having a power density in the range 0.15 to 2.0 W/cm2, preferably in the range 0.2 to 0.5 W/cm2, at a frequency of greater than 1.1 MHz, preferably 1.1 MHz to 10 MHz, more preferably 1.1 MHz to 5 MHz or having a frequency of greater than 1.1 MHz, in which the treatment area is not subjected to a rise of greater than 3°C.The invention also provides a kit for the treatment of skin and/or subcutaneous tissue, and in particular for the treatment of cellulite in a treatment area, the kit including a device comprising an ultrasound energy source; an applicator for applying the ultrasound energy to the treatment area; and a composition adapted to be applied to the skin at the region where the ultrasound energy is applied.The present method and kit provide improved therapeutic skin ageing and/or cellulite treatment or prevention, improved safety in use and are suitable for general domestic or non-clinical use.

Method and Kit for the Treatment or Prevention of Cosmetic Skin Conditions

Field of the Invention

The present invention relates to a method for the treatment or prevention of cosmetic skin conditions such as regional fat deposits including cellulite, and in particular for the cosmetic treatment of regional fat deposits including cellulite using ultrasound. The method comprises exposing a selected area either to non heating ultrasound having a time average power density in the range 0.15 to 2.0 W/cm^2 and a frequency of greater than 1.1 MHz or to ultrasound having a frequency of greater than 1.1 MHz in which the surface of the selected area is not subjected to a temperature rise of greater than 3°C.

The invention further relates to a kit for the treatment or prevention of cosmetic skin conditions such as regional fat deposits including cellulite. The kit includes a device comprising a source of ultrasound energy and an applicator for applying the ultrasound energy to a selected area and a composition adapted to be either applied to the skin at, or adjacent, the region where the ultrasound energy is applied or ingested by the user. More particularly, this invention relates to a kit wherein the therapeutic application of low power, non heating ultrasound to the skin is enhanced by the simultaneous or sequential administration of a composition (either an oral composition or a topical composition or both), thus allowing a more effective treatment of the skin.

Background to the Invention

As we age, and as a normal course of hormonal fluctuations, environmental influences and individual genetic tendencies, skin elasticity is gradually reduced. At the same time, lean tissue mass decreases and adipose tissue increases. Generally speaking, adipose tissue tends to concentrate the body's fat stores in a few regional sites of the body, such as the mid-section, the thighs and buttocks, and/or the back of the arms. In some regions,

especially the legs, bulging of fat chambers near the skin's surface can cause dimpling of the skin at the attachment points of the skin's underlying structural fibrous strands. This regional fat deposit is termed cellulite and it occurs most often on the thighs, hips, waist, buttocks and upper arms of women. Cellulite is a cosmetic rather than a medical condition.

The dimpling of the skin affected by cellulite is also known as the "orange peel" effect, and it is an undesirable cosmetic condition that affects women of all ages and sizes, although it is generally more prevalent in women who are overweight to some degree. In a society that is increasingly concerned with image, women have resorted to many methods to try to rid themselves of cellulite.

To date, many creams for the treatment of cellulite have been available on the market. Relatively expensive to buy, their results are often minimal and short-lived. Dry-brushing is another method suggested for the treatment of cellulite, which involves the frequent brushing of oneself with relative vigour with the bristles of a suitable brush. The method of dry-brushing, however, leaves the skin feeling relatively uncomfortable and raw, and it also often has a minimal effect on the cellulite.

There has been a desire in recent years to provide a different method of treating regional fat deposits including cellulite which is both effective and relatively painfree.

Cellulite is not the only cosmetic condition that concerns women. Stretch marks are another example of a cosmetic condition which affects not only women, but also men. Stretch marks can form at various stages of a person's life, for example, at puberty, during pregnancy in the case of women, or generally when a person gains a substantial amount of weight. Stretch marks are most commonly found on the thighs, buttocks and abdomen, but also quite frequently appear on other areas, the upper arms for example. The stretch marks appear as generally purple blemishes on the skin, generally quite long and thin, with a length dependable on the position of the body on which they are found and the

reason for the formation of the stretch marks. Over time, the stretch marks fade in colour and eventually have a silver appearance. It is virtually impossible to rid oneself of stretch marks using conventional methods. Loss of weight will result in their appearance being less noticeable but they are still present on the skin. Creams are available on the market which claim to reduce the appearance of the stretch marks, but the effect of these creams are generally minimal and short-lived, similar to the effects of the creams for the treatment of cellulite.

US6113559, which is incorporated herein by reference, discloses a method and apparatus of reducing human skin wrinkles which involves applying a focused ultrasound beam to a region of human skin so that energy is deposited in the dermis layer sufficient to heat tissue within the layer in order to stimulate or irritate the layer thereby causing a change in the dermis layer that results in a change in smoothness of the epidermis layer. Specifically, US6113559 discloses an ultrasound power density of 100-500 W/cm^2 and a frequency of 1-500 MHz.

The use of ultrasound therapy specifically for the treatment of cellulite is also known and the application of ultrasonic wave energy has generally proven effective in the breaking down of subcutaneous fatty tissue.

For example, EP695559, which is incorporated herein by reference, relates to multifunctional equipment for beauty treatments such as cellulitis, which may include emitters of ultrasonic vibrations for application to, for example, the thighs of a patient's body. However, EP695559 does not disclose or suggest either a suitable power density or a suitable frequency.

GB2303552, which is incorporated herein by reference, discloses an ultrasound apparatus for the non-invasive reduction of cellulite. The device allows the ultrasonic treatment of cellulite at a predetermined frequency of about 3.3 MHz and a typical power density of

2.8 W/cm^2, with 50% of the energy being absorbed within a depth of from 1.27cm to 2.54cm below the skin surface.

US6030374, which is incorporated herein by reference, relates to a method for enhancing the transport of an active agent through skin in which the skin is exposed to ultrasound and an active agent is applied to the skin by injection. The active agent may, *inter alia*, be used to reduce the appearance of cellulite. Typically, for lower frequency ultrasound, an ultrasound frequency between 25 kHz and 3 MHz at a power density of 0.5-2.0 W/cm^2 is used and typically, for higher frequency ultrasound, an ultrasound frequency between 3 MHz and 16 MHz at a power density of 0.2-1.0 W/cm^2 is used.

US5665053, which is incorporated herein by reference, relates to an endermology body massager having ultrasound generators that are selectively controlled by the operator. However, the very low frequency long wave ultrasound disclosed - 10 to 40 kHz - is in the range typically known as disruptive ultrasound, which may be damaging to cells, and thus is not suitable for general use except at very low power levels, for safety reasons.

US5507790, which is incorporated herein by reference, discloses apparatus for focusing ultrasound energy to raise the temperature of a work site within the patient's subcutaneous adipose tissue layer to between 40.0 and 41.5°C in order to accelerate local fat tissue lipolysis reaction rates. The apparatus includes an ultrasonic transducer which supplies ultrasound energy of an undisclosed frequency and at an undisclosed power density to a focusing element.

Ultrasound can be used to improve transdermal drug delivery. For example, WO 99/34857, which is incorporated herein by reference, discloses transdermal drug delivery of various active agents including agents for treating cellulite. A power density of less than 20 W/cm^2, preferably less than 10 W/cm^2, is disclosed. A frequency of less than 2.5 MHz, preferably less than 2 MHz, preferably less than 1 MHz, most preferably 20-100 kHz is disclosed, whilst ultrasound at a frequency of 20 kHz and a power density of 1 or

1.5 or 7 W/cm^2 was exemplified *in vivo* on rats. Similarly, US4767402, which is incorporated herein by reference, discloses transdermal drug delivery using ultrasound at a power density of 0-3 W/cm^2, preferably 0.5-1.5 MHz, whilst a power density of 1-2 W/cm^2 at a frequency is 870 kHz is exemplified. However, US4767402 teaches that, as the power density is reduced, the frequency should also be reduced.

However, such known ultrasound therapy methods involve the use of relatively high power ultrasound, for example in the region of greater than about 1 watt. The use of relatively high power ultrasound has safety implications and typically a maximum of 3 watts cm^{-2} is set by health and safety requirements.

Surprisingly, it has been found that the use of low to moderate power, high frequency, non heating ultrasound therapy on a skin treatment area results in an improved response in the treatment of cosmetic skin conditions such as regional fat deposits including cellulite. In addition, the use of low power, high frequency, non heating ultrasound therapy, for example having a frequency of greater than 1.1 MHz and either a power density in the range of 0.15 to 2.0 W/cm^2 or requiring that the surface of the selected area is not subjected to a temperature rise of greater than 3°C, allows the method of the invention to be used effectively yet safely in a domestic or non-clinical environment.

Surprisingly, it has also been found that, when the method includes either applying a topical composition to the selected area of the skin and/or ingesting an oral composition before exposing the selected area to the ultrasound, a more efficient treatment of cosmetic skin conditions such as regional fat deposits including cellulite can be achieved. Thus, the use of high frequency, non-heating, ultrasound has been found to synergistically improve penetration of the active ingredient of the composition. Without wishing to be bound by theory, it is believed that ultrasound at low to moderate power causes streaming effects near cells, promoting a rise in intracellular calcium levels. These ions act as secondary messengers in processes involved in tissue repair by signalling the cells, e.g. fibroblasts, to increase synthesis of cAMP and collagen and, therefore, comprise a biostimulation

mechanism. The synergy with the topical and/or oral composition is believed to come from providing, at the same time, active agents either to complement the growth of healthy tissue, e.g., by supporting tissue revascularisation (a mechanism offered by, for example, retinyl palmitate); or to promote lipolysis leading to, in turn, reduction of subcutaneous fat and reduced pressure on the dermis (or cellulite treatment) (a mechanism afforded by, for example, theophylline).

It is an object of the present invention to provide a method which enables the efficient treatment of an area of the skin and/or subcutaneous tissue, and in particular the cosmetic treatment or prevention of skin conditions such as regional fat deposits including cellulite, using non heating, high frequency ultrasound therapy.

It is a further object of the present invention to provide a kit for the improved cosmetic treatment of skin and/or subcutaneous tissue, and in particular for the treatment of cosmetic skin conditions such as regional fat deposits including cellulite in a selected area, using non heating, high frequency ultrasound therapy. It is a still further object of the present invention to provide a method or kit which uses high frequency, non-heating portable devices which are suitable for domestic use or unsupervised use in clinics. These, and other objects of this invention, will become apparent in the light of the following disclosure.

Summary of the Invention

The present invention relates to a method for the treatment or prevention of cosmetic skin conditions and in particular for the treatment of regional fat deposits including cellulite, comprising exposing a selected area of the skin and/or subcutaneous tissue to ultrasound having a power density in the range 0.15 to 2.0 W/cm^2, more preferably in the range 0.2 to 0.5 W/cm^2, and a frequency of greater than about 1.1 MHz, preferably about 1.1 to about 10 MHz, more preferably 1.1 MHz to about 5 MHz, most preferably about 1.1 MHz to about 3.5 MHz.

The present invention also relates to a method for the treatment or prevention of cosmetic skin conditions, and in particular for the cosmetic treatment of regional fat deposits including cellulite, the method comprising exposing a selected area of the skin and/or subcutaneous tissue to ultrasound having a frequency of greater than 1.1 MHz, in which the surface of the selected area is not subjected to a temperature rise of greater than 3°C.

The present invention also further relates to a method for the treatment or prevention of cosmetic skin conditions and in particular for the cosmetic treatment of regional fat deposits including cellulite, comprising the steps of exposing a selected area of the skin and/or subcutaneous tissue to ultrasound having a power density in the range of 0.15 to 2.0 W/cm^2 and a frequency of greater than 1.1 MHz; and exposing the selected area, or an area adjacent thereto, to a source of at least one alternative energy form selected from the group comprising light, electrotherapy, active massage, static magnets, heat, compression and combinations of two or more thereof.

The present invention further relates to a kit for the treatment or prevention of cosmetic skin conditions and in particular for the treatment or prevention of regional fat deposits including cellulite at a selected area of the skin and/or subcutaneous tissue, the kit including a device comprising an ultrasound energy source and an applicator for applying the ultrasound energy to the selected area; and a composition adapted to be either applied to the skin at, or adjacent, the selected area or adapted to be ingested by the user.

Preferably, the kit further comprises a light source, preferably in the form of one or more LED's, for applying light energy to the selected area.

Brief Description of the Figures

Figure 1 illustrates a schematic diagram of a device according to the present invention.

Figure 2 illustrates a schematic of an electrostatic device that can be used in conjunction with devices of the present invention, shown to include the steady state current flow for one half of an alternating current cycle.

Detailed Description of the Invention

All publications cited herein are hereby incorporated by reference in their entirety, unless otherwise indicated.

As used herein, the term "subcutaneous tissue" means tissue lying beneath the skin and includes adipose tissue and subcutaneous fat.

As used herein, the term "regional fat deposits" means areas of excessive fat, of which cellulite is an example, and excess fatty tissue.

As used herein, the term "cellulite" means deposits of fat, which generally do not respond to dieting and exercise.

As used herein, the term "light" means monochromatic, dichromatic or multichromatic electromagnetic radiation in the visible or infrared ranges. The use of light in the treatment of cosmetic skin conditions and/or subcutaneous tissue, and in particular regional fat deposits including cellulite in human skin, comprises exposing the area of treatment to a source of electromagnetic radiation, preferably having a wavelength of from approximately 600 nanometers to approximately 1100 nanometers. The electromagnetic radiation may be applied by means of one or more LED's, one or more lasers, one or more light bulbs, or any other suitable source of electromagnetic radiation. The electromagnetic radiation may be coherent or non-coherent, pulsed or continuous, or combinations thereof.

As used herein, the term "electrotherapy" means the application of either a static or active electric current to the treatment site, and may include such applications as muscular electrical nerve stimulation (MENS), transcutaneous electrical nerve stimulation (TENS), and iontophoresis, but is not intended to be limited thereto.

As used herein, the term "static magnet" means a magnet with a static magnetic field having an intensity of from 100 to 2000 gauss, the magnet, in use, imparting a monopolar or bipolar magnetic polarity to the body of a user. The use of static magnets in the treatment of regional fat deposits including cellulite preferably involves exposing an area of skin and/or subcutaneous tissue, and in particular cellulite in human skin, to the static magnetic field thereof.

As used herein, the term "active massage" means the stimulation of biological tissue by physical or mechanical means. Massaging tissue involves application of stress from outside the tissue, either compression or tension (both are beneficial). The stress can be applied randomly or directionally, for example, directed in the direction of the lymph flow. Non-limiting examples of massaging devices are percussive, roller, pinching and vacuum massagers, and combinations thereof. Massage to cellulite skin, stimulates flow of lymph; increases blood flow; stretches the connective tissue fibers; remodels the dermal interface with the subcutaneous adipose tissue; and promotes cellular activity via stress-orientation

As used herein, the term "laser" means light amplification by stimulated emission of radiation.

As used herein, the term "topical" means designed for or involving local application and action.

As used herein, the term "ultrasound" means pressure waves having a frequency of at least 16 kHz, preferably at least 20 kHz, the application of which may be either

continuous or pulsed. Pulsed ultrasound is effectively a train of pulses. For example, ultrasound can be delivered in an "on-off" mode, where the unit pulses on for 0.2 seconds, then off for 0.8 seconds, with this cycle being repeated indefinitely. Pulsing is typically used for high energy input uses. The "off" time allows heat that may have built up in one area to diffuse away, such that no localised hot spots result. For the present invention, pulsing is acceptable and will produce the desired results, but continuous wave ultrasound is preferred.

As used herein, the term "compression" means the application of static pressure by wrapping or otherwise, increasing the pressure in the tissues.

As used herein, the term "non-heating" means that, during application of the ultrasound, no more than a 3°C rise, preferably no more than a 2°C rise, more preferably no more than a 1°C rise, in temperature of the skin surface can be detected, by the method now described.

Skin Temperature Increase Method

Skin average temperature in the region to which ultrasonic energy is to be applied is measured. A thermocouple with relatively low thermal mass is selected, such as a YSI Precision 4000 A Thermometer made by Yellow Springs Instrument Company, Inc., Yellow Springs, OH, USA, with 400 Series flat probe, or similar. The thermocouple probe measures 1 cm across. The thermocouple is taped with low strength adhesive tape (e.g., masking tape) to an area of the skin to maintain its thermal mass at skin temperature before and between all temperature measurements. An area of skin measuring at least 20 cm^2 area is selected and temperature is measured at at least 3 locations within the region by holding the thermocouple on the skin for about 10-20 seconds until the probe has equilibrated, and the result averaged. Treatment is applied to the region of skin, including any coupling fluid and ultrasonic energy. Immediately following treatment, coupling fluid is wiped off quickly and the thermocouple is again held on the skin in the treated

area, and temperature measured as before. If after 20 seconds a steady equilibrium temperature has not been reached, the temperature value at 20 seconds is taken. The temperature rise is expressed as the final temperature minus the initial average temperature, in degrees Celsius.

Ultrasonic energy (using a Mettler Sonicater 730) was applied from a 5 cm^2 probe to an area of skin on the outer thigh (*in vivo*) measuring 25.8 cm^2. Power density was adjusted as well as treatment time for different experiments. A mediating gel was used between the probe and the skin during ultrasound application, which had a cooling effect. A control experiment was included (no power, but with gel and probe). Temperature was measured with the aforementioned thermocouple to within 0.03°C prior to and following treatment, taking multiple measurements quickly in the treatment area and averaging the results. All of these ultrasound treatments were continuous, not pulsed.

Treatment power and treatment time	Temperature Change	Total power (Watts)	Energy applied (Power/Watts x time/seconds)	Tissue Energy Density (Energy per unit area of tissue)
Control (no power)	-1.56°C	0	0	0
1 W/cm^2, 1 min	-0.83°C	5	300 Joules	11.6 J/cm^2
2 W/cm^2, 1 min	+0.50°C	10	600 Joules	23.3 J/cm^2
1 W/cm^2, 4 min	+0.95°C	5	1,200 Joules	46.5 J/cm^2
2 W/cm^2, 3 min	+3.69°C	10	1,800 Joules	69.8 J/cm^2

It is an object of one embodiment of the present invention to limit the temperature rise on the skin to a maximum of 3° C. According to the table above, the Tissue Energy Density should be kept to less than about 55 J/cm^2 utilising this equipment and energy application protocol. Thus, if a larger, 10 cm^2 probe is used at a power density of 2 $Watts/cm^2$ power

level, the application time could be calculated as follows: Assume the area of tissue to which energy is to be applied is a 300 cm^2 area of the thigh. Calculating:

[10 cm^2 probe] x [2 Watts/ cm^2 power] x [T seconds application time] ÷ [300 cm^2 tissue] < 55 J/ cm^2

Solving, T = 825 seconds, or about 14 minutes application time. Thus, even at a power density of 2 W/ cm^2, the temperature rise can be restricted to 3°C or less, as long as the probe moves around the area during application.

The mediating fluid used in this experiment was a hydrophilic gel (Sonigel Water Soluble couplant sold by Mettler Electronics Corp., 1333 South Clauding St, Anaheim, CA, USA) which provided some cooling due to evaporation. Oil based coupling fluids would not provide same cooling effect, thus a 3°C temperature rise would be achieved with a lower ultrasound energy input.

As used herein, the term "wearable device", which includes the term "sleeve", means a substantially flexible section of material in the form of, for example, a wrap, patch, cuff or a bandage which may be placed on, conform to or which may be held adjacent a selected area of the body. Such a wrap, patch, cuff or bandage may be formed from a substrate, preferably a disposable substrate. The sleeve may, in addition, be dimensioned and adapted to apply compression. The sleeve in the form of a wrap, patch, cuff or bandage may be held in place by the use of straps or fasteners. For example, one side of the sleeve may be connected to the other side of the sleeve, using buttons, Velcro (Trade Mark) or the like. Alternatively, the sleeve may be adapted to form a shape which is specifically designed to fit on an arm, leg, buttocks, stomach or other selected body part. The sleeve may therefore be in the form of a garment such as a sock, trousers, shorts or the like. The material which forms the sleeve is generally flexible and may also have a degree of elasticity. The flexible nature of the sleeve enables the sleeve to conform to the desired shape, and, for example, to enable the sleeve to be pulled up over the selected area of the

body. The optionally elastic nature of the sleeve facilitates the sleeve to fit the selected body part in a suitably tight yet comfortable manner.

Cosmetic Skin Conditions

The term "cosmetic skin conditions", as used herein, includes signs of skin ageing and regional fat deposits including cellulite. "Signs of skin ageing" include, but are not limited to, all outward visibly and tactilely perceptible manifestations as well as any other macro or micro effects due to skin ageing. Such signs may be induced or caused by intrinsic or extrinsic factors, e.g., chronological ageing and/or environmental damage (e.g., sunlight, UV, smoke, ozone, pollutants, stress, etc.). These signs may result from processes which include, but are not limited to, the development of textural discontinuities such as wrinkles, including both fine superficial wrinkles and coarse deep wrinkles, skin lines, facial frown lines, expression lines, rhytides, dermatoheliosis, photodamage, premature skin ageing, crevices, bumps, pits, large pores (e.g., associated with adnexal structures such as sweat gland ducts, sebaceous glands, or hair follicles), "orange peel" skin appearance, dryness, scaliness, flakiness and/or other forms of skin unevenness or roughness; excess skin oil problems such as over-production of sebum, oiliness, facial shine, foundation breakthrough; abnormal desquamation (or exfoliation) or abnormal epidermal differentiation (e.g., abnormal skin turnover) such as scaliness, flakiness, keratoses, hyperkeratinization; inadequate skin moisturization (or hydration) such as caused by skin barrier damage, environmental dryness; loss of skin elasticity (loss and/or inactivation of functional skin elastin) such as elastosis, sagging (including puffiness in the eye area and jowls), loss of skin firmness, loss of skin tightness, loss of skin recoil from deformation; non-melanin skin discoloration such as undereye circles, blotching (e.g., uneven red coloration due to, e.g., rosacea), sallowness (pale colour), discoloration caused by telangiectasia; melanin-related hyperpigmented (or unevenly pigmented) skin regions; post-inflammatory hyperpigmentation such as that which occurs following an inflammatory event (e.g., an acne lesion, in-grown hair, insect/spider bite or sting, scratch, cut, wound, abrasion, and the like); atrophy such as, but not limited to, that

associated with ageing or steroid use; other histological or microscopic alterations in skin components such as ground substance (e.g., hyaluronic acid, glycosaminoglycans, etc.), collagen breakdown and structural alterations or abnormalities (e.g., changes in the stratum corneum, dermis, epidermis, the skin vascular system such as telangiectasia); tissue responses to insult such as itch or pruritus; and alterations to underlying tissues (e.g., subcutaneous fat, cellulite, muscles, trabeculae, septae, and the like), especially those proximate to the skin.

Topical Compositions : Carriers

It is envisaged that topical compositions may perform both pharmaceutical and/or cosmetic functions.

The topical carrier compositions of the present invention can comprise a carrier. The carrier should be "dermatologically acceptable", which means that the carrier is suitable for topical application to the skin, has good aesthetic properties, is compatible with the remaining components, and will not cause any untoward safety or toxicity concerns. A safe and effective amount of carrier is from about 50% to about 99.99%, preferably from about 80% to about 99.9%, more preferably from about 90% to about 98%, most preferably from about 90% to about 95% of the composition.

The carrier can be in a wide variety of forms. For example, emulsion carriers, including, but not limited to, oil-in-water, water-in-oil, water-in-oil-in-water, and oil-in-water-in-silicone emulsions, are useful herein. These emulsions can cover a broad range of viscosities, e.g., from about 100 cps to about 200,000 cps (at room temperature). These emulsions can also be delivered in the form of sprays using either mechanical pump containers or pressurised aerosol containers using conventional propellants. These carriers can also be delivered in the form of a mousse. Other suitable topical carriers include anhydrous liquid solvents such as oils, alcohols, and silicones (e.g., mineral oil, ethanol, isopropanol, dimethicone, cyclomethicone, and the like); aqueous-based single phase

liquid solvents (e.g., hydro-alcoholic solvent systems); and thickened versions of these anhydrous and aqueous-based single phase solvents (e.g., where the viscosity of the solvent has been increased to form a solid or semi-solid by the addition of appropriate gums, resins, waxes, polymers, salts, and the like). Examples of topical carrier systems useful in the present invention are described in the following four references all of which are incorporated herein by reference in their entirety: "Sun Products Formulary" Cosmetics & Toiletries, vol. 105, pp. 122-139 (December 1990); "Sun Products Formulary", Cosmetics & Toiletries, vol. 102, pp. 117-136 (March 1987); US 4,960,764 to Figueroa et al., issued Oct. 2, 1990; and US 4,254,105 to Fukuda et al., issued Mar. 3, 1981. A further discussion of suitable carriers is found in US 5,605,894 to Blank *et al*, and US 5,681,852 to Bissett, both of which are herein incorporated by reference in their entirety.

Topical Compositions : Skin Actives

The compositions of the present invention may optionally comprise one or more skin actives. By the term "skin active" is meant an agent that promotes the growth of healthy skin tissue by, for example, supporting tissue revascularisation. Non-limiting examples of such skin actives include vitamin B3 compounds such as those described in WO 97/39733, published Oct. 30, 1997, to Oblong et al., herein incorporated by reference in its entirety; hydroxy acids such as salicylic acid; anti-oxidants/radical scavengers such as tocopherol and esters thereof; metal chelators, especially iron chelators; retinoids such as retinol, retinyl palmitate, retinyl acetate, retinyl propionate, and retinal; N-acetyl-L-cysteine and derivatives thereof; hydroxy acids such as glycolic acid; keto acids such as pyruvic acid; benzofuran derivatives; and anti-cellulite agents (e.g., xanthines such as caffeine, theophylline); niacinamide, which promotes healthy cell growth in the dermis; polycyclic compounds such as triterperoids (e.g., betulinic acid); and sterols such as stigmasterol. Mixtures of any of the above mentioned skin actives may also be used. A more detailed description of these actives is found in US 5,605,894 to Blank et al (previously incorporated by reference).

Other conventional active ingredients, or mixtures thereof, may also be included. These include exfoliation or desquamatory agents such as zwitterionic surfactants; sunscreens such as 2-ethylhexyl-p-methoxycinnamate, 4,4'-t-butyl methoxydibenzoyl-methane, octocrylene, phenyl benzimidazole sulfonic acid; sun-blocks such as zinc oxide and titanium dioxide; anti-inflammatory agents; depilatory agents (e.g., sulfhydryl compounds); skin lightening agents (e.g., arbutin, kojic acid, hydroquinone, ascorbic acid and derivatives such as ascorbyl phosphate salts, placental extract, and the like); moisturizing agents; anti-microbial agents; anti-androgens; and skin protectants. Ultraviolet absorbing agents, often described as sunscreening agents, can be present in a concentration in the range of between about 1% and about 12% by weight, based on the total weight of composition. Preferably, the UV absorbing agents constitute between about 2% and 8% by weight. More preferably, the UV absorbing agents can be present in the composition in a concentration range of between about 4% and about 6% by weight. Of the ultraviolet absorbing agents suitable for use herein, benzophenone-3, octyl - dimethyl PABA (Padimate O), Parsol MCX, and mixtures thereof are particularly preferred. Also useful in topical compositions of the present invention are sunless tanning agents including dihydroxyacetone, glyceraldehyde, indoles and their derivatives, and the like. These sunless tanning agents can also be used in combination with the sunscreen agents.

An optional skin active of the topical compositions of the present invention is a flavonoid compound - an aromatic compound having two substituted benzene rings connected by a chain of three carbon atoms and an oxygen bridge. Flavonoids are broadly disclosed in US 5,686,082 and US 5,686,367, both of which are herein incorporated by reference. Flavonoids suitable for use in the present invention are flavanones selected from the group consisting of unsubstituted flavanones, mono-substituted flavanones, and mixtures thereof; chalcones selected from the group consisting of unsubstituted chalcones, mono-substituted chalcones, di-substituted chalcones, tri-substituted chalcones, and mixtures thereof; flavones selected from the group consisting of unsubstituted flavones, mono-

substituted flavones, di-substituted flavones, and mixtures thereof; one or more isoflavones; coumarins selected from the group consisting of unsubstituted coumarins, mono-substituted coumarins, di-substituted coumarins, and mixtures thereof, chromones selected from the group consisting of unsubstituted chromones, mono-substituted chromones (including 3-formyl chromone), di-substituted chromones, and mixtures thereof; one or more dicoumarols; one or more chromanones; one or more chromanols; isomers (e.g., cis/trans isomers) thereof, and mixtures thereof. By the term "substituted" as used herein means flavonoids wherein one or more hydrogen atom of the flavonoid has been independently replaced with hydroxyl, C_1-C_8 alkyl, C_1-C_4 alkoxyl, O-glycoside, and the like or a mixture of these substituents.

The flavonoid compounds can be synthetic materials or obtained as extracts from natural sources (e.g., plants). The naturally sourced material can also further be derivatized (e.g., an ester or ether derivative prepared following extraction from a natural source). Flavonoid compounds useful herein are commercially available from a number of sources, e.g., Indofine Chemical Company, Inc. (Somerville, N.J.), Steraloids, Inc. (Wilton, N.H.), and Aldrich Chemical Company, Inc. (Milwaukee, Wis.). Preferred naturally sourced materials include kava root (standardised to give a kavalactone content of about 30% by wt and containing the full spectrum of lactones found in the kava plant) and green tea solids containing the full range of green tea polyphenols (i.e. catechins and epicatechins). - such materials may, optionally, be ingested as part of an oral composition.

Mixtures of flavonoid compounds may also be used.

Other suitable skin actives are discussed in further detail in WO 97/39733, published Oct. 30, 1997, to Oblong et al, previously incorporated by reference in its entirety.

Optional Components : Topical Compositions

Compositions optionally comprise a pigment or mixture of pigments. The pigment used herein must be compatible with any acidic skin care active which may be present in the

composition and have excellent overall colour stability. Suitable pigments for use herein can be inorganic and/or organic. Also included within the term pigment are materials having a low colour or lustre such as matte finishing agents, and also light scattering agents. Examples of suitable pigments are iron oxides, rutile titanium dioxide, anatase titanium dioxide, ferric oxide, ferrous oxide, chromium oxide, chromium hydroxide, manganese violet, acylglutamate iron oxides, ultramarine blue, D&C dyes, carmine, and mixtures thereof. Depending upon the type of make-up composition, e.g. foundation or blusher, a mixture of pigments will normally be used.

If the composition is a foundation, then the foundation composition can also include at least one matte finishing agent. The function of the matte finishing agent is to hide skin defects and reduce shine. Such cosmetically acceptable inorganic agents, i.e., those included in the CTFA Cosmetic Ingredient Dictionary, Third Ed., as silica, hydrated silica, silicone-treated silica beads, mica, talc, polyethylene, titanium dioxide, bentonite, hectorite, kaolin, chalk, diatomaceous earth, attapulgite zinc oxide and the like may be utilized.

An optional component of the topical compositions herein is a humectant or mixture of humectants, which can act as skin conditioners and are, therefore, to be considered as skin actives. The humectant or mixture of humectants herein is optionally present in an amount of from about 0.1% to about 30% preferably from about 1% to about 25%, and more preferably from about 1% to about 10% by weight of composition. Other conventional skin care product additives may also be included in the compositions of the present invention. For example, urea, guanidine and mixtures thereof may be used. Glycerine is a preferred humectant.

The topical compositions herein can additionally comprise an emollient. Emollients suitable for the compositions of the present invention include natural and synthetic oils selected from mineral, vegetable, and animal oils, fats and waxes, such as petroleum, fatty

acid esters, fatty alcohols, alkylene glycol and polyalkylene glycol ethers and esters, fatty acids and mixtures thereof.

Another optional component herein is one or more additional chelating agents, preferably in the range of from about 0.02% to about 0.10% by weight, based on the total weight of the composition. Preferably, the chelating agent is present in a concentration in the range of between about 0.03% and about 0.07% by weight, based on the total weight of the composition. Among the chelating agents that may be included in the composition is tetrasodium EDTA.

Another optional but preferred component of the topical composition is one or more preservatives. The preservative concentration in the composition, based on the total weight of that composition, is in the range of between about 0.05% and about 0.8%, preferably between about 0.1% and about 0.3%. Suitable preservatives for use herein include sodium benzoate and propyl paraben, and mixtures thereof.

Oral Compositions

Oral compositions are generally intended either to induce satiety/promote nutrient malabsorption and thereby indirectly enhance thermogenesis and/or to directly, enhance thermogenesis to consume fat/calories and/or stimulate metabolic activity in general and lipolytic activity in particular.

Oral dosage forms are optional compositions for use in the present invention and these include the known forms for such administration, for example tablets, capsules, granules, syrups and aqueous or oil suspensions. Any carriers known in the art for oral application compositions may be used. For solid form preparations, such as, for example, powders, tablets, disbursable granules and capsules, a solid carrier may be one or more substances such as diluents, flavoring agents, solubilizers, lubricants, suspending agents, binders, tablet disintegrating agents, encapsulating materials and the like. Suitable carrier materials

may include, for example, magnesium carbonate, calcium carbonate, sodium bicarbonate, magnesium stearate, calcium stearate, talc, lactose, sugar, pectin, dextrin, starch, tragacanth, cellulose derivatives, methyl cellulose, sodium carboxymethyl cellulose, a low-melting wax, cocoa butter, alginates, gelatin, polyvinyl pyrrolidone, polyethyl glycols, quaternary ammonium compounds and the like.

Tablets may be prepared from an active agent (nutrient absorption suppressant(s) and/or thermogenic agents) or a mixture thereof (see below), with fillers, for example, calcium phosphate; disintegrating agents, for example, maize, starch; lubricating agents, for example, magnesium stearate; binders, for example, microcrystalline cellulose or polyvinylpyrrolidone and other optional ingredients known in the art to permit tableting the mixture by known methods. The tablets may, if desired, be coated using known methods and excipients which may include enteric coating using for example hydroxypropylmethylcellulose phthalate. The tablets may be formulated in a manner known to those skilled in the art so as to give a sustained release of a suitable active agent(s). Such tablets may, if desired, be provided with enteric coatings by known methods, for example by the use of cellulose acetate phthalate. Similarly, capsules, for example hard or soft gelatin capsules, containing the active agent(s) with or without added excipients, may be prepared by known methods and, if desired, provided with enteric coatings in a known manner. The contents of the capsule may be formulated using known methods so as to give sustained release of the active agent(s).

Other dosage forms for oral administration include, for example, aqueous suspensions containing an active agent(s) in an aqueous medium in the presence of a non-toxic suspending agent such as sodium carboxymethylcellulose, and oily suspensions containing the active agent(s) in a suitable vegetable oil, for example arachis oil. The active agent(s) may be formulated into granules with or without additional excipients.

The granules may be ingested directly by the patient or they may be added to a suitable liquid carrier (for example, water) before ingestion. The granules may contain

disintegrants, e.g. an effervescent couple formed from an acid and a carbonate or bicarbonate salt to facilitate dispersion in the liquid medium.

Nutrient Absorption Suppressants : Oral Compositions

Active agents which act on the central nervous system (CNS) to suppress appetite and, therefore, suppress nutrient absorption may be used in the present oral compositions. One major subclass of CNS appetite suppressant drugs interacts with catecholaminergic receptors in the brainstem. These include controlled drugs such as amphetamine, phenmetrazine, and diethylproprion, and over-the-counter drugs such as phenylpropanolamine. Manizidol is another CNS active drug which, although not a catecholamine, activates the central nervous system. Oleic acid and salts and esters thereof are preferred nutrient absorption suppressants.

Other suitable active agents are drugs which promote malabsorption of nutrients through suppression of digestive enzymes. One agent in this category is Acarbose, a bacterial inhibitor of amylase and brushborder glycosidases. Another is tetrahydrolipostatin, a fungal inhibitor of lipases. These agents work by preventing digestion of carbohydrates and/or fats, thus creating an effective reduction in the number of calories absorbed, despite continued consumption.

Satiety inducing agents induce a feeling of satiety (suppress appetite) resulting in a net reduction in caloric intake following ingestion, shifting the balance of the body to enhanced thermogenesis. Oleic acid and its esters are preferred satiety inducing agents.

Thermogenic Agents : Oral or Topical Compositions

Thermogenic agents, which act by promoting either metabolic activity in general or lipolytic activity in particular, may also be included in the present oral compositions. The catecholamine drugs discussed above have some thermogenic activity, in addition to their suppression of appetite. Thyroid hormone is also optionally used. The thermogenic agent

may also include one or more of kola nut, N-acetyl-L-carnitine, cayenne extract, salicin, niacin or a derivative thereof (including niacinamide) or inositol hexanicotinate. N-acetyl-L-carnitine is useful in facilitating the transport of fat into mitochondria for their metabilization to generate energy. Cayenne extract stimulates the production of energy in the form of adenosine triphosphate (ATP) which, in turn, metabolizes more fat. Salicin, which is found naturally in the bark of the white willow, also has been implicated in the stimulation of thermogenesis. Niacin, also known as vitamin B-3, and its derivatives are known to induce thermogenesis and act to lower low density lipoprotein (LDL) cholesterol levels and elevate high density lipoprotein (HDL) cholesterol levels. It does so by reducing lipoprotein synthesis in the liver.

Agents which have a heating effect when applied on the skin, e.g., rubifacients, are also considered to be thermogenic agents.

Lipolytic agents are preferred thermogenic agents. A large number of active lipolytic agents may be used in the present compositions, such as asiatic acid; methylxanthines including caffeine, theophylline and aminophylline; nicotinic acid derivatives, such as α-tocopherol nicotinate or hexyl nicotinate; silicon; carnitine; coenzyme Q; escin; ruscogenin; draining, firming, lipolytic or veinotropic plant extracts; anti-glucose-uptake active agents; α-2-blocker compounds capable of blocking the α-2 receptors at the surface of adipocytes, such as ginkgo biloba; keratolytic agents, such as 5-octanoylsalicylic acid; salicylic acid; α-hydroxy acids such as lactic acid, malic acid, glycolic acid or tartaric acid or α-hydroxy acids from fruit, such as citric acid; polyethylene glycol fatty acid esters, glycerophosphatides, phosphatidylephosphates, egg yolk lecithin, oleic acid, stearic acid, palmitate, cholesterol, mono, di, and tri-glycerides, cholesterol ester, yolk lecithin containing 5 to 20% phosphatidic acid, linoleic acid, linolenic acid, lauric acid, phosphatidyl phosphate, glycerine, soy bean oil, sesame seed oil, and tromethan. Green tea solids induce thermogenesis by acting on adipocyte cells, thereby reducing fat mass of the body.

The following examples demonstrate the following for treatment of regional fat deposits including cellulite:-

1. The device itself, and in combination with other devices
2. The device as a kit with topical compositions
3. Device, topical composition and oral composition as a kit or programme
4. At least 1 of the elements above with a monitoring function as part of a programme (%body fat monitoring, e.g.) or a business practice - home monitoring or at a spa, exercise club, etc.

As additional disclosure, the topical compositions include active agents for treating regional fat deposits including cellulite, with the object of rebuilding the dermis (stimulate collagen, revasculaturize); anti-inflammatory action; anti-histamine action; lipolysis; hormonal therapy; and/or thermogenesis.

Without wishing to be bound by theory, it is believed that the action of the device (including the device combinations) achieves its objective by one or more of the following mechanisms; biostimulation and generally enhanced cellular activity; enhanced streaming; enhanced lymphatic drainage; promotion of tissue vascularization; cavitation; and/or increased blood flow (massage, heat, etc.)

Example 1

Therapeutic ultrasound treatment is provided using a commercially available ultrasound apparatus (Mettler Sonicator 730, available from Mettler Electronics Corporation (http://www.mettlerelec.com/ultrasnd.html)). Ultrasound energy at 3 MHz is applied through a hand-held transducer which has a 5 cm^2 skin contact area. A mediating gel (for example, Sonigel by Metter Electronics Corp. Andheim, CA-a water soluble gel) is spread one the outer thighs of on subject prior to treatment. Ultrasound energy is continuously applied at a power density of 0.2 Watts per square centimetre (W/cm^2) to an area of the thigh measuring about 300 cm^2 for a period of 15 minutes. The ultrasound probe is continuously moved in a slow, circular motion within the treatment area. Over the 15 minute treatment period, the skin temperature did not rise by more than 1°C. Treatments

are applied on alternating days for a period of 12 weeks to reduce the signs of ageing and/or the appearance of cellulite.

Example 2

Therapeutic ultrasound treatment is provided using the same commercially available ultrasound apparatus as Example 1. Ultrasound energy at 1.5 MHz is applied through a hand-held transducer which has a 10 cm^2 skin contact area. A mediating gel is spread on the outer thighs of the subject prior to treatment. Ultrasound energy is applied at a power density of 1.0 Watt per square centimetre (W/cm^2) with a 50% duty cycle to an area of the thigh measuring about 300 cm^2 for a period of 12 minutes. Thus, ultrasound energy is applied at a time average power density of 0.5 W/cm^2. The ultrasound probe is continuously moved in a rapid, circular motion within the treatment area to avoid build up of heat within the tissues - the skin temperature did not rise by more than 1°C. Treatments are applied daily for a period of 12 weeks to reduce signs of ageing and/or the appearance of cellulite.

Example 3

An anticellulite device 10 is prepared which, as illustrated in Figure 1, is a combination of a massaging device and an ultrasonic energy device, for the treatment of the conditions of skin ageing and/or cellulite. A housing 12 is prepared containing space for two ultrasound transducers 14 and a massaging skin roller 16. Two 5 cm^2 3.3 MHz Mettler ultrasound transducer probes 14 are fitted into the housing to provide ultrasound energy. The housing additionally provides a well containing a transverse mounted shaft with protruding skin massaging rubber-like elements 18, which provide percussive type massage as the housing 12 is moved across the skin. The ultrasound probes 14 are connected to respective Mettler Sonicator 730 power supplies 20 continuously operating at a power density of 0.6 W/cm^2 each. A mediating gel is used to promote absorption of the ultrasound waves. The housing 12 is moved back and forth manually across the thigh area of a woman with signs of cellulite and/or skin ageing for 10 minutes on each leg to

treat the condition by the synergistic combination of massage to stimulate the tissue and ultrasound energy to promote healthy blood supply.

Example 4

A topical composition is prepared and used together with an ultrasound device of the present invention.

The topical composition is prepared by combining and mixing the ingredients using conventional technology and then applying about 0.5g to about 50g of the resultant topical composition to the skin.

Ingredient	% Weight
Glycerine	6.933
Niacinamide	14.00
Theophylline	1.500
Caffeine	0.500
Permethyl 101A[1]	3.000
Sepigel[2]	2.500
Q2-1403[3]	2.000
Isopropyl Isostearate	1.330
Arlatone 2121[4]	1.000
Cetyl Alcohol CO-1695	0.720
SEFA Cottonate[5]	0.670
Tocopherol Acetate	0.500
Panthenol	0.500
Adol 62[6]	0.480
Kobo Titanium Dioxide	0.400
Sodium Hydroxide 50% Aqueous	0.0150
Fiery 5[7]	0.150

Disodium EDTA	0.100
Glydant Plus[8]	0.100
Myrj 59[9]	0.100
Emersol 132[10]	0.100
Colour	0.00165
Purified Water	q.s. to 100

[1]Isohexadecane, Presperse Inc., South Plainfield, NJ; [2]Polyacrylamide(and)C13-14 Isoparaffin(and)Laureth-7, Seppic Corporation, Fairfield, NJ; [3]dimethicone(and)dimethiconol, Dow Corning Corp., Midland, MI; [4]Sorbitan Monostearate and Sucrococoate, ICI Americas Inc., Wilmington, DE; [5]Sucrose ester of fatty acid, Procter and Gamble, Cincinnati, OH; [6]Stearyl alcohol, Procter and Gamble, Cincinnati, OH; [7]Fiery, Procter and Gamble, Cincinnati, OH; [8]DMDM Hydantoin (and) Iodopropynyl Butylcarbamate, Lonza Inc., Fairlawn, NJ; [9]PEG-100 Stearate, ICI Americas Inc., Wilmington, DE; [10]Stearic acid, Henkel Corp., Kankakee, IL.

The composition is applied to the thighs of a woman showing signs of cellulite. Immediately following application of the skin cream, the rolling massage-ultrasound device of Example 3 is used to massage the cream into the skin for 10 minutes on each thigh. No coupling fluid is needed as the composition serves as a couplant.

Example 5

A topical composition is prepared and used together with an ultrasound device of the present invention.

Ingredient	Content (% W/W)
Carboxyvinyl polymer	0.300
Propylene glycol	5.00
Methylparaben	0.15

Ascorbic Acid	0.10
Glyceryl monostearate	5.00
Cetanol	1.00
Stearyl alcohol	0.50
White Petrolatum	1.50
BHT	0.05
Propylparaben	0.10
Butylparaben	0.05
Cetyl palmitate	1.00
C_{12}-C_{15} Alkyl Benzoate	4.00
Benzyl alcohol	0.30
Ethyl alcohol	4.00
Disodium EDTA	0.05
Retinyl palmitate	0.30
Sodium Hydroxide (10%)	to adjust pH to 8.0
Water	QS

An emulsion is prepared by first preparing the water phase and then preparing the oil phase. After both phases are separately prepared, they are mixed together and retinyl palmitate is added.

The water phase is made by first weighing deionized water into a beaker and, with mixing at high speed, slowly adding carboxy polymer. EDTA and ascorbic acid are then added to the mixture and mixing is continued until well-dissolved, about 40 minutes. The water phase is then heated to 80°C, at which time propylene glycol is added.

To make the oil phase, all ingredients of the oil phase are weighed and added together in a separate beaker, heating to 80°C with mixing until homogeneous.

The oil phase is then slowly poured into the water phase with mixing. Sodium hydroxide is added at 80°C in order to adjust the pH of the emulsion. After mixing for ten minutes, the emulsion is cooled to 45°C. Retinyl palmitate is then added to the emulsion and the emulsion is mixed until homogeneous. The procedure is carried out under yellow light and under an nitrogen blanket so as to minimise exposure to oxygen.

The therapeutic ultrasound device of Example 2 is used, with a mediating gel, to massage the skin for 15 minutes on each leg. Immediately following the massage, excess mediating gel is wiped off, and the composition is applied to treat the signs of cellulite.

Example 6

A patient exhibiting signs of cellulite and/or skin ageing is treated with a multi-step program including a vacuum-massage, application of ultrasound, and a topical composition.

A topical composition in the form of a cosmetic cream mousse is prepared comprising the following ingredients:

INGREDIENTS	Weight (%)
Step A	
Water	59.20
Cetyl Hydoxyethylcellulose	0.50
Step B	
Water	28.00
Citric A acid	0.20
Sodium Citrate	0.35
Dihydroxyacetone	3.00
Erythrulose	0.75
Step C	

Methyl Gluceth 20	1.00
Glycerin	1.00
1,2-Pentandiol	3.00
2-Methyl-1,3-Propanediol	0.50
Decyl Glucoside	1.00
Phenonip (TM)	0.30
PPG-5 Ceteth	1.00
Step D	
Fragrance	0.20

Methyl gluceth 20 is obtained from Amerchol Corp (Edison, N.J.) as Glucam E-20, 1,2-pentandiol is obtained from Dragoco (Totowa, N.J.) as Hydrolite-5, 2-methyl-1,3-propanediol is obtained from Lyondell (Newtown, Pa.) as MP Diol Glycol, decyl glucoside is obtained from Henkel Corp. (Amber, Pa.) as Plantaren 2000, Phenonip TM (a blend of phenoxyethanol, methylparaben, ethylparaben, propylparaben, and butylparaben) is obtained from NIPA Corp.(Williamstown, Del.), and PPG-5 Cetearth-20 is obtained from Croda Corp (Parsippany, N.J.) as Procetyl AWS.

The water and cetyl hydroxyethylcellulose (Natrosol Plus CS 300, Hercules Incorporated, Wilmington, Del.) of Step A are mixed and heated up to 70°C and the temperature maintained until the polymer is completely hydrated ("Step A Mixture"). The water, citric acid, and sodium citrate of Step B are added, and the mixture is mixed and cooled until the citric acid and sodium citrate dissolve. Once the temperature falls below 40°C, the dihydroxyacetone (Rona, Hawthorne, N.Y.) and erythrulose (Pentapharm, Ltd., Basel, Switzerland) are added to the mixture ("Mixture AB"). All of the ingredients of Step C are mixed together in a mixer.

Once a homogenous solution is achieved, the fragrance is added. Optionally, about 0.1 wt% microfine titanium dioxide can be dispersed into Step A to achieve a skin opacifying

benefit. The mixture is stirred well until the fragrance dissolves ("Mixture CD"). Mixture CD is then added to Mixture AB, and the resulting mixture is mixed well. The resulting self-tanning mousse has a pH of 4-4.8.

A massage is given to the buttocks and thigh regions of a patient that exhibit signs of cellulite and/or skin ageing, for 15 minutes using a commercially available anti-cellulite pinching roller vacuum device, the Cellesse SenseActive HP5231 device manufactured by Philips, Inc. The device applies both a massaging effect and a vacuum suction to the tissues. Then, the ultrasound device of Example 2 is massaged over the same area of the skin for 15 minutes. Both of the aforementioned two massage elements may be integrated into a single device and, indeed, this is preferred. The cream mousse is applied topically to the thighs. The procedure is repeated at least once every other day. The topical composition promotes a rapid reduction in cellulite appearance noticeable within a few days, while the extended application of energy from the massagers and ultrasound reduce the signs of cellulite in the tissues themselves as part of an extended program.

Example 7

An area of a patient's thigh which exhibits signs of cellulite is treated with electrical energy, ultrasound energy, and mechanical massage. Integration of the energies into a single device is preferred, although each may be separately provided.

An electrical device is prepared. The device applies alternating electrical current to tissues from an electrostatic hand-held device. The device is prepared according to Figure 2 and applies an electrostatic potential magnitude of about 2,000 volts to the skin, alternating in polarity. One commercial embodiment of this device is represented by the Beautiko Oxygen Pen, marketed in the United Kingdom by the Beautiko Company. The electrostatic device consists of a conventional circuit 10 ranged to effect the electrostatic application of a current from the outside of a glass bulb 36 to the skin, and also in the opposite direction. The circuit 110 includes an alternating electrical current source 112, at a voltage of 100 volts, in order to provide an electric current to the glass bulb 136. The

circuit 110 includes a first capacitor 114 having a capacitance of 0.47 μF, a first resistor 116 with a resistance of 3.3 MΩ, a second resistor 118 having a resistance of 1.5 kΩ, a second capacitor 124 having a capacitance of 0.47 μF, a third resistor 126 having a resistance of 2 MΩ, a fourth resistor 128 having a resistance of 22 kΩ, a variable resistor 130 having a maximum resistance of 20 kΩ, and a fuse 134 to prevent overloading of the circuit 110. The circuit 110 also includes a plurality of diodes 132 disposed between the various components, to insure the correct flow of current through the circuit 110. The circuit 110 additionally includes a first coil 120, and a second coil 122 disposed in close proximity to the first coil 120, the second coil 122 having a relatively large number of windings. Both the first coil 120 and the second coil 122 are disposed within the glass bulb 136.

The device is fabricated inside a plastic housing, permanently insulating the electronic components away from the user. Both the 1st coil 120 and the 2nd coil 122 are recessed inside the vapor filled glass bulb 136, which diffuses electrical current as it flows from the 2nd coil 122 to the glass bulb 136 and vice versa, depending on the phase of the alternating electrical current source. As the 2nd capacitor 124 discharges through the first coil 122, the rapid growth and collapse of the electromagnetic field induces a current in the second coil, which acts as a transformer with a spark gap at the tip, discharging electrostatically through the glass bulb 136. Figure 2 of the drawings shows the circuit 110 illustrating the steady state current flow for one half of the alternating current cycle. The adjustable resistor is set to apply maximum electrostatic potential through the skin contact bulb (about one half inch diameter), and an isolated area of a woman's outer thigh is treated with the device. The area treated measures approximately 20 square inches. The site is treated by moving the device slowly in a circular motion over the skin for 22 minutes. Laser doppler blood flow of the electrostatically treated area prior to and 15 minutes after electrostatic treatment confirms improved circulation to the area. 15 minutes after electrostatic treatment, the same area of the skin is treated with the ultrasonic massaging device of Example 3. After the massage, the topical composition of Example 5 is applied to the skin. The composition absorbs into the skin rapidly due to

enhanced permeability of the stratum corneum resulting from application of the electrostatic energy. The treatment is repeated as often as necessary until the signs of cellulite are reduced.

Example 8

A kit is prepared comprising an oral composition in the form of a dietary supplement as a beverage, together with the elements of Example 7.

An oral composition is prepared as follows. A single packet of a dry instant beverage mix is blended with 8.0 grams of oleic acid. The dry instant beverage mix is sold by Nestle ® Carnation ® as French Vanilla flavoured Instant Breakfast ™ Nutritional Energy Drink (or similar) and comprises about 36.3 grams of dry instant mix. The dry mix contains these ingredients: nonfat dry milk, maltodextrin, sugar, cellulose gum, natural and artificial vanilla flavour, dicalcium phosphate, magnesium hydrochloride, sodium ascorbate, ferric orthophosphate, vitamin E acetate, niacinamide, copper gluconate, zinc oxide, calcium pantothenate, manganese sulfate, vitamin A palmitate, pyridoxine hydrochloride, thiamin mononitrate, folic acid, biotin, phylloquinone, vitamin B12. The oleic acid is stirred into the dry mixture. A dietary supplement beverage is prepared from the resulting mixture by stirring into 8 fluid ounces of skim milk. The beverage (oral composition) is consumed as breakfast (in place of other food for breakfast) as part of an extended program to reduce the appearance of cellulite. The beverage (oral composition) induces a feeling of satiety resulting in a net reduction of caloric intake over the course of the day the beverage is consumed, contributing to a reduction in cellulite, as part of the program. The dietary supplement beverage is used with the electrical, ultrasonic and massaging devices and topical composition of Example 7 as part of a program to reduce the signs of cellulite.

Example 9

An area of a patient's thigh which exhibits signs of regional fat deposits including cellulite is treated with light energy and ultrasound energy. A light patch array is fabricated using

Gallium Arsenide Phosphide on Gallium Phosphide red light emitting diodes (LEDs) which illuminate maximally at about 635 nm. Spectral analysis is verified with a spectrometer, for example Ocean Optics SD2000 High Sensitivity Fiber Optic Spectrometer with OOiBase32 PC software, from Ocean Optics, Inc. Agilent Technologies HLMP-1340 T-1 diodes are used. Each of the diodes measures approximately 3 mm diameter with transparent lenses and a 45 degree viewing angle. An individual diode delivers about 0.10 milliwatts (mW) optical power at 1.85 volts; 0.16 mW optical power at 1.95 volts; and 0.32 mW optical power at 2.14 volts, drawing 8.0, 15.1 and 30.3 milliamps (mA) current, respectively, at the specified voltages. Optical power is measured with a multifunctional optical power meter, for example an Oriel OPM Model 70310 with enhanced UV Silicone Detector, a 1 cm square array, and the LED positioned as close as possible to the detector (8 mm). The LEDs are connected in parallel by soldering to a standard rigid printed circuit board with 0.1 inch (0.254cm) grid using a diode density of 25 two-pin diodes per square inch (6.45cm^2) (i.e., 50% of PC board capacity). The PC board measures 6 inches (15.24cm) by 4 inches (10.16cm), with 438 diodes covering an inner 5 inch (12.7cm) by 3.5 inch (8.89cm) rectangular area of the board. Two six-cell rechargeable NiMH batteries are connected in series to deliver power through a DC-DC switching converter to reduce voltage to approximately 2.0 volts, and the voltage is trimmed using an adjustment circuit and potentiometer to deliver 1.95 volts to the array, measured across each diode. The array has an optical power of about 0.60 mW/cm^2. A small, battery powered fan is affixed to the back of the array to remove excess heat generated during use. The array is affixed to an elastic neoprene sleeve (5 mm thick) measuring about 25 inches (63.5cm) long by 8.5 inches (21.59cm) wide that has two, 2-inch (5.08cm) wide elastic straps that extend another 10 inches (25.4cm) in length. The straps are attachable and detachable to the bulk of the sleeve by a hook and loop type fastening system, to affix the sleeve to the thigh while concurrently allowing therapeutic compression to be applied. A rectangular hole is cut in the center of the neoprene sleeve, and straps located at its edge to allow the light patch array to sit within the sleeve. Wires connect the array to the power supply. The power supply and battery are contained in a pouch with a hook to attach to the belt or waistband of the user, so the

sleeve can be worn while the user is active. The sleeve is attached to the thigh of a user to treat regional fat deposits including cellulite, the power supply switched on, and the user resumes normal activity for a period of between 0.5 and 2 hours, applying about 1 to 4 Joules/cm^2 (J/cm^2). After this period, the sleeve is rotated or moved to apply energy to a different site, moved to the other leg, or removed. By applying energy to different sites, the entire thigh is treated with light and therapeutic compression. After about 4 hours of continuous use, the batteries are recharged to prepare them for another cycle.

Therapeutic ultrasound treatment is provided using a commercially available ultrasound apparatus (Mettler Sonicator 730, available from Mettler Electronics Corporation (http://www.mettlerelec.com/ultrasnd.html)). Ultrasound energy at 3 MHz is applied through a hand-held transducer which has a 5 cm^2 skin contact area. A mediating gel such as Sonigel Water Soluble gel available from the Mettler Electronics Corporation, Anaheim, CA, USA is spread on the outer thighs of a subject prior to treatment. Ultrasound energy is continuously applied at a power density of 0.2 Watts per square centimetre (W/cm^2) to an area of the thigh measuring about 300 cm^2 for a period of 15 minutes. The ultrasound probe is continuously moved in a slow, circular motion within the treatment area. Over the 15 minute treatment period, the skin temperature did not rise by more than 1°C. Treatments are applied on alternating days for a period of 12 weeks to reduce the signs of ageing and/or the appearance of regional fat deposits including cellulite.

A daily regimen includes application of the energy treatments to different spots on each leg. It will be appreciated that the light energy and the ultrasound energy can be applied either sequentially or simultaneously depending on the treatment required. Integration of the energies into a single treatment device is preferred, although each may be separately provided.

The above described arrangements are merely illustrative of the principles of the present invention. Other modifications and adaptations may occur to those skilled in the art, without departing from the spirit and scope of the present invention.

Example 10

Therapeutic ultrasound treatment is provided using a commercially available ultrasound apparatus (Mettler Sonicator 730, available from Mettler Electronics Corporation (http://www.mettlerelec.com/ultrasnd.html)). Ultrasound energy at 3 MHz is applied through a hand-held transducer which has a 5 cm^2 skin contact area. A mediating gel is spread on the outer thighs of on subject prior to treatment. Ultrasound energy is continuously applied at a power density of 0.2 Watts per square centimetre (W/cm^2) to an area of the thigh measuring about 300 cm^2 for a period of 15 minutes. The ultrasound probe is continuously moved in a slow, circular motion within the treatment area. Following the ultrasound treatment the bicycle shorts of Example 1 are applied to treat the regional fat deposits as described, for the same treatment duration described in Example 1.

The above described arrangements are merely illustrative of the principles of the present invention. Other modifications or adaptations may occur to those skilled in the art, without departing from the spirit and scope of the present invention.

Claims:

1. A method for the treatment or prevention of cosmetic skin conditions, and in particular for the cosmetic treatment of regional fat deposits including cellulite, comprising exposing a selected area of the skin and/or subcutaneous tissue to ultrasound having a power density in the range 0.15 to 2.0 W/cm^2 at a frequency of greater than 1.1 MHz.

2. A method for the treatment or prevention of cosmetic skin conditions, and in particular for the cosmetic treatment of regional fat deposits including cellulite, the method comprising exposing a selected area of the skin and/or subcutaneous tissue to ultrasound having a frequency of greater than 1.1 MHz, in which the surface of the selected area is not subjected to a temperature rise of greater than 3°C.

3. A method according to Claim 1 or 2 wherein the power density is in the range 0.2 to 0.5 W/cm^2.

4. A method according to Claim 1 or 2 wherein the ultrasound energy is applied directly to the selected area.

5. A method according to any of Claims 1 to 4 wherein the method includes either;
   applying a topical composition to the selected area of the skin, or an area adjacent thereto, before, during or after exposing the selected area, or an area adjacent thereto, to the ultrasound; or
   ingesting an oral composition before, during or after exposing the selected area, or an area adjacent thereto, to the ultrasound.

6. A method according to Claim 5, wherein the method includes:
   applying a topical composition to the selected area of the skin, or an area adjacent thereto, before, during or after exposing the selected area to the ultrasound; or

ingesting an oral composition before, during or after exposing the selected area, or an area adjacent thereto, to the ultrasound.

7. A method according to any of Claims 1 to 5 wherein the selected area, or an area adjacent thereto, is subjected to the ultrasound by means of the application of an applicator to the selected area, or an area adjacent thereto, the applicator being adapted to be vibrated by an ultrasound generator which generates ultrasound vibrations.

8. A method according to any of Claims 1 to 7 wherein the ultrasound frequency is in the range 1.1 MHz to 10 MHz, preferably 1.1 MHz to 5 MHz, most preferably 1.1 MHz to 3.5 MHz.

9. A method according to any of Claims 1 to 8 wherein the ultrasound is applied to the selected area, or an area adjacent thereto, continuously over a predetermined period of time.

10. A method according to any of Claims 1 to 8 wherein the ultrasound is applied to the selected area, or an area adjacent thereto, in pulsed mode over a predetermined period of time.

11. A method according to Claim 9 or 10 wherein the predetermined period of time is in the range about 0.5 minute to about 30 minutes, preferably about 2 minutes to about 25 minutes, more preferably about 3 minutes to about 20 minutes, most preferably about 5 minutes to about 15 minutes.

12. A method according to any preceding claim comprising the additional step of exposing the selected area, or an area adjacent thereto, to a source of at least one alternative energy form selected from the group comprising light, electrotherapy,

active massage, static magnets, compression and combinations of two or more thereof.

13. A kit for the treatment or prevention of cosmetic skin conditions, and in particular for the treatment or prevention of regional fat deposits including cellulite at a selected area of the skin and/or subcutaneous tissue, the kit including:
    (i) a device comprising an ultrasound energy source; and an applicator for applying the ultrasound energy to the selected area, or an area adjacent thereto; and
    (ii) a topical composition adapted to be applied to the skin at, or adjacent, the selected area and/or an oral composition for ingestion.

14. A kit according to Claim 13 further including a device comprising at least one alternative energy form selected from the group comprising light, electrotherapy, active massage, static magnets, compression and combinations of two or more thereof.

15. A kit according to Claim 14 wherein the alternative energy form is light in the form of one or more LED's.

16. A kit according to Claim 13 wherein the ultrasound energy comprises low power, non heating ultrasound having a power density in the range 0.15 to 2.0 W/cm^2 at a frequency of greater than 1.1 MHz.

17. A kit according to Claim 13 wherein the ultrasound energy comprises ultrasound having a frequency of greater than 1.1 MHz in which, in use, the surface of the selected area is not subjected to a temperature rise of greater than 3°C.

18. A kit according to any Claims 13 to 16 wherein both a topical composition and an oral composition are present.

19. A kit according to any of Claims 13 to 18 wherein the power density is in the range 0.2 to 0.5 W/cm^2.

20. A kit according to any of Claims 13 to 19 wherein the topical composition includes an active agent selected from theophylline, aminophylline, niacinamide and retinyl palmitate.

21 A kit according to any of Claims 13 to 20 wherein the oral composition includes an active agent selected from caffeine, a soy extract, a soy isolate including a soy isoflavone.

22. A method according to Claim 12 wherein the selected area is simultaneously exposed to the ultrasound and to the, or each, alternative energy form source.

23. A method according to Claim 12 wherein the selected area, or an area adjacent thereto, is sequentially exposed, in either order, to the ultrasound and to the, or each, alternative energy form source.

INTERNATIONAL SEARCH REPORT

Int itional Application No
PCT/US 02/14504

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N7/00 A61K7/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61K A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	column 1, line 7 - line 11 claims 1,2,5	15,20,21
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/14504

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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